

REMARKS/ARGUMENTS

With this amendment, claims 2, 3, and 16-26 are pending. New claim 27 is added. For convenience, the Examiner's rejections are addressed in the order presented in a September 2, 2004, Office Action and a January 13, 2005 Advisory Action is also discussed.

I. Status of the claims

Claim 2 is amended to recite a recombinant nucleic acid that comprises a nucleic acid sequence having at least 98% identity to a reference sequence, *e.g.*, SEQ ID NO:1, 3, or 5. Claim 21 is amended to recite a recombinant nucleic acid that comprises a nucleic acid sequence having at least 99% identity to a reference sequence, *e.g.*, SEQ ID NO:1, 3, or 5. Support for these amendments is found throughout the specification, for example at page 18, lines 30-35. These amendments add no new matter.

Claim 16 is amended to recite a nucleic acid sequence that encodes a MINK3 protein having at least 98% identity to a reference sequence, *e.g.*, SEQ ID NO:2, 4, or 6. Claim 22 is amended to recite a nucleic acid sequence that encodes a MINK3 protein having at least 99% identity to a reference sequence, *e.g.*, SEQ ID NO:2, 4, or 6. Support for these amendments is found throughout the specification, for example at page 15, lines 1-7. These amendments add no new matter.

New claim 27 is added and is directed to a recombinant nucleic acid that comprises a nucleotide sequence complementary to the nucleic acid sequences of claims 2 or 16. Support for this amendment is found throughout the specification, for example at page 4, lines 29-32. This amendment adds no new matter.

II. Response to January 13, 2005 Advisory Action

Based on the Advisory Action mailed on January 13, 2005, it is the understanding of the Applicants that the amendments and remarks herein overcome the rejections of claims 2, 3, and 16-26 under 35 U.S.C. §112, for alleged lack of written description and under 35 U.S.C. §103(a) in view of cited art.

The Advisory Action indicated that new claim 27 would be rejected for alleged lack of written description under 35 U.S.C. §112, first paragraph. Claim 27 is directed to recombinant nucleic acid sequences that are complementary to nucleic acid sequences of claims 2 or 16. Applicants respectfully point out that claim 27 has written description in the application at, *e.g.*, page 4, lines 29-32; page 20, lines 4-6; and at original claims 1-3. Moreover the MPEP has indicated that the written description requirement does not require individual support for each species in a genus. As an example, written description is provided for a claim directed to a nucleic acid sequence that encodes a particular amino acid sequence, a genus with potentially millions of members. MPEP 2163 IIA3(a)ii. Here, those of skill would immediately recognize that only a particular nucleic acid sequence has few complementary sequences, and would immediately be able to identify a complementary sequence based on the well known hydrogen bonding pattern between bases in complementary strands of a nucleic acid duplex, *e.g.*, A binds to T, and C binds to G. In view of these arguments, Applicants respectfully request withdrawal of any rejection of claim 27 under 35 U.S.C., 112, first paragraph for alleged lack of written description.

III. Rejections under 35 U.S.C. §112, first paragraph, written description

Claims 2, 3, and 21 are rejected under 35 U.S.C. §112, first paragraph as allegedly containing subject matter that was not described in specification. The Office Action points out that the purpose of the written description requirement is to demonstrate that the inventors had possession of the claimed invention at the time of filing. The Office Action first objects to the term "complement" in claims 2, 3 and 21, alleging, for example, that the Applicants are not in possession of a complementary strand of SEQ ID NO:1 that encodes a MINK3 protein. In order to expedite prosecution, claims 2, 3 and 21 are amended and no longer recite "complement" or similar terms. In view of these amendments, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, first paragraph.

IV. Rejections under 35 U.S.C. §102(b)

Claims 2, 3, 16-18, 19, 20, and 22-26 are rejected as allegedly anticipated by various references under 35 U.S.C. §102(b). To the extent the rejection applies to the amended claims, Applicants respectfully traverse the rejection.

To anticipate a claim, the reference must teach every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found...in a single prior art reference." *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Thus, in order to anticipate, the cited references must contain every element of the claims at issue. The cited references do not.

The amended claims now recite 98% or 99% identity to a reference sequence. Applicants assert again the cited references fail to disclose all the elements of the amended claims. Moreover, at a minimum, claims directed to the exact reference sequences, *i.e.*, claims 3, and 23, are allowable. In addition, Applicants object to sequence alignments apparently used by the Office Action to find anticipation of the claims. As discussed below for each cited sequence, the sequence alignments were used incorrectly and some sequences were improperly cited as prior art.

A. Rejection of claims 2, 3, and 16-18 in view of Ippeita et al.

Claims 2, 3, and 16-18 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Ippeita *et al.*, *FEBS Letters* 469:19023 (2000). Applicants respectfully remind the Examiner that analysis of a claimed sequence must be performed on the entire sequence; using portions of a claimed sequence to obtain a finding of anticipation is improper. In addition, references cannot be cited as prior art unless they were publicly available before the filing date of the present application.

For nucleic acid analysis, the Office Action compares a nucleic acid from Accession number AB03598 to SEQ ID NO:1 and alleges that over 96% identity is shared by the two sequences. This analysis is incorrect. The alignment sent with the Office Action improperly uses only a portion of the full length SEQ ID NO:1. Applicants submit as Exhibit A, an alignment between SEQ ID NO:1 and the nucleic acid sequence of Accession Number AB03598

demonstrating that the sequences share only 95.4% identity. Applicants submit that, using similar analysis, SEQ ID NO: 3 and 5 share less than 96% identity with the cited nucleic acid sequence. Thus, the % identity value cited by the Office Action is incorrect and the amended claims are not anticipated by the nucleotide sequence of Accession Number AB03598.

For amino acid sequence analysis, the Office Action improperly cites a sequence that was not publicly available until well after the filing date of the present application. The Office Action asserts that the MINK1 disclosure of Ippeita *et al.* is more than 99% identical to the claimed reference amino acid sequence. Unfortunately, the Office Action did not use the amino acid sequence discussed by Ippeita *et al.* to perform alignment analysis. The MINK1 amino acid sequence referred to in Ippeita *et al.* is found at Accession Number AB03598. *See, Ippeita et al.* at page 20, paragraph 2.10. Instead, the Office Action used an amino acid from Accession Number Q8N4C8. Applicants submit as Exhibit B an NCBI Sequence Revision History from the Entrez website, indicating that Accession Number Q8N4C8 was first seen at NCBI on April 1, 2003, well after the October 19, 2001 filing date of the present invention. Applicants submit as Exhibit C an alignment between the amino acid sequence of Accession Number AB03598 (*i.e.*, the sequence of Ippeita *et al.*) and SEQ ID NO:2 of the present invention. SEQ ID NO:2 and the amino acid sequence of Accession Number AB03598 share only 95.6% identity, and Applicants submit that, using similar analysis, SEQ ID NO: 4 and 6 also share less than 96% identity with the cited amino acid sequence. Thus, the claimed subject matter was not taught by a prior disclosure of properly cited MINK1 sequences.

B. Rejection of claims 2, 3, and 16-18 in view of Plowman et al.

Claims 2, 3, and 16-18 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Plowman *et al.*, US Patent No. 6,656,716 ('716 patent). Again, Applicants respectfully remind the Examiner that analysis of a claimed sequence must be performed on the entire sequence; using portions of a claimed sequence to obtain a finding of anticipation is improper.

For nucleic acid analysis, Office Action compares SEQ ID NO:11 from the '716 patent to SEQ ID NO:1 of the present application and alleges that over 95% identity is shared by

the two sequences. This analysis is incorrect. The alignment sent with the Office Action improperly uses only a portion of the full length SEQ ID NO:1 (*i.e.*, begins at nucleotide 110) and also truncates cited SEQ ID NO:11 (ending with nucleotide 3987 of 4133). Applicants submit as Exhibit D, an alignment between full length SEQ ID NO:1 and full length SEQ ID NO:11 from the '716 patent demonstrating that the sequences have only 90.2% identity. Applicants submit that, using similar analysis, SEQ ID NO: 3 and 5 also have identities of less than 95% to the cited nucleic acid reference sequence. Thus, the % identity value cited by the Office Action is incorrect and the amended claims are not anticipated by the nucleotide sequence of SEQ ID NO:11 from the '716 patent.

For amino acid analysis, Office Action compares SEQ ID NO:15 from the '716 patent to SEQ ID NO:2 of the present application and reports that over 95% identity is shared between the two sequences. This analysis is incorrect. The alignment sent with the Office Action improperly uses only a portion of the full length SEQ ID NO:2 (*i.e.*, begins at amino acid 36). Applicants submit as Exhibit E, an alignment between full length SEQ ID NO:2 and full length SEQ ID NO:15 from the '716 patent demonstrating that the sequences share only 93.3% identity. Applicants submit that, using similar analysis, SEQ ID NO: 3 and 5 also have identities of less than 95% to the cited nucleic acid reference sequence. Thus, the % identity value cited by the Office Action is incorrect and the amended claims are not anticipated by the nucleotide sequence of SEQ ID NO:15 from the '716 patent.

C. Rejection of claims 19, 20, and 22-26 in view of Ippeita et al.

Claims 19, 20, and 22-26 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Ippeita *et al.* because, according to the Office Action, the reference discloses sequences with at least 96% identity to the claimed nucleic acid sequences and with at least 99% identity to the claimed amino acid sequences.

Applicants respectfully remind the Examiner that, in order to anticipate a claim, a reference must teach each and every element of the claim. Claims 19, 20, and 22-26 each directly or indirectly depend from claim 2. Thus, each claim recites an amino acid or a nucleic acid with at least 98% identity to a reference sequence. The deficiencies of Ippeita *et al.* are

described in detail above, in particular, the failure of Ippeita *et al.* to teach nucleic acids with at least 98% identity to SEQ ID NO:1, 3, or 5 or amino acids with at least 98% identity to SEQ ID NO:2, 4, or 6. As Ippeita *et al.* fail to teach the nucleic acid or amino acid sequences required by claims 19, 20, and 22-26, the reference cannot anticipate those claims.

In view of the above amendments and arguments, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §102(b).

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,


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